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EXAMINER
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ART UNIT	PAPER NUMBER
1623	

NOTIFICATION DATE	DELIVERY MODE
04/21/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/533,538	KIRIBAYASHI ET AL.	
	Examiner	Art Unit	
	MICHAEL C. HENRY	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 November 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/23/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The following office action is a responsive to the appeal brief filed on November 24, 2010. Upon further review and consideration of the appeal brief it was decided that the prosecution should be reopened due to the Information Disclosure Statement (IDS) filed by Applicant September 23, 2010 which was not considered by the Examiner and consequently to better respond to Applicant's claimed invention. The responsive to the appeal brief is contained herein below.

In view of the appeal brief filed on 11/24/10, PROSECUTION IS HEREBY REOPENED. A new ground of rejection is set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/SHAOJIA ANNA JIANG/

Supervisory Patent Examiner, Art Unit 1623

Claims 11-36 are pending in the application and examined on the merits herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 34 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites the phrase "peritoneal dialysis solution that does not contain adenosine triphosphate and adenosine triphosphate." However, the claim is indefinite since it is unclear how a solution can contain and simultaneously not contain the same substance or ingredient (adenosine triphosphate).

The following is a new ground(s) of rejection necessitated by Applicant's submission of an information disclosure statement under 37 CFR 1.97 on September 23, 2010.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11, 18, 21, 29, 33 are rejected under 35 U.S.C. 102(b) as anticipated by Yurzhenko ("Parenteral nutrition in the program of therapy of diffuse peritonitis (Russian)", XP002597104, Elsevier Science Publishers, Amsterdam, NL, 1973, Vol. 18, No. 7, pp. 36-38, Cited by Applicant IDS filed September 23, 2010).

Claim 11 is drawn to a peritoneal dialysis method for treating a peritoneal injury or for treating a cell injury caused by sugar comprising: administering to a patient having a peritoneal injury or a cell injury caused by sugar a dialysate comprising adenosine triphosphate or a salt thereof. Yurzhenko discloses Applicant's method for treating a peritoneal injury comprising: administering to a patient having a peritoneal injury a dialysate comprising adenosine triphosphate (see abstract). It should be noted that the examiner considers peritonitis as a peritoneal injury or peritoneal cell injury. In fact, it should be noted that applicants acknowledge in their specification that examples of the peritoneal injuries include peritonitis, sclerotic encysted peritonitis, intractable prolonged peritonitis, and general peritonitis (see page 2, paragraph [0026] of applicants' specification).

Claim 18 is drawn to a treating method for peritoneal injury, characterized by administering an effective amount of adenosine triphosphate or a salt thereof to a subject in need thereof. Yurzhenko discloses Applicant's treating method for peritoneal injury, characterized by administering an effective amount of adenosine triphosphate to a subject in need thereof (see abstract). It should be noted that the examiner considers peritonitis as a peritoneal injury or peritoneal cell injury. In fact, it should be noted that applicants acknowledge in their specification that examples of the peritoneal injuries include peritonitis, sclerotic encysted

peritonitis, intractable prolonged peritonitis, and general peritonitis (see page 2, paragraph [0026] of applicants' specification).

Claim 21 is drawn to a peritoneal dialysis method for treating a peritoneal injury or for treating a cell injury caused by sugar, comprising: administering into the peritoneal cavity of a subject having a peritoneal injury or a cell injury caused by sugar an effective amount of a composition comprising adenosine triphosphate. Yurzhenko discloses Applicant's peritoneal dialysis method for treating a peritoneal injury comprising administering into the peritoneal cavity of a subject having a peritoneal injury an effective amount of a composition comprising adenosine triphosphate (see abstract). It should be noted that the examiner considers peritonitis as a peritoneal injury or peritoneal cell injury. In fact, it should be noted that applicants acknowledge in their specification that examples of the peritoneal injuries include peritonitis, sclerotic encysted peritonitis, intractable prolonged peritonitis, and general peritonitis (see page 2, paragraph [0026] of applicants' specification). Claim 29 is also anticipated by since Yurzhenko's patient or subject also has peritonitis (see abstract).

Claim 33 is drawn to a peritoneal dialysis method comprising: administering to a patient in need of dialysis a dialysate comprising adenosine triphosphate or a salt thereof. Yurzhenko discloses Applicant's method comprising administering to a patient a dialysate comprising adenosine triphosphate (ATP) (see abstract).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11, 12, 14, 16-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Isono et al. (US 5,871,477, of record).

Claim 11 is drawn to a peritoneal dialysis method for treating a peritoneal injury or for treating a cell injury caused by sugar comprising: administering to a patient having a peritoneal injury or a cell injury caused by sugar a dialysate comprising adenosine triphosphate or a salt thereof. Claim 12 is drawn to the peritoneal dialysis method of claim 11, wherein said patient is suffering from a renal disease, and said dialysate is administered intraperitoneally via a catheter implanted in the peritoneal cavity. Claims 13-17 are drawn to said method wherein the adenosine triphosphate or a salt thereof is of specific concentration range, wherein the composition further comprises glucose, and an electrolyte, glucose of specific concentration range and further administering high level glucose.

Isono et al. disclose a peritoneal dialysate composition comprising 1 to 8 g/dL glucose (i.e., 1,000- 8000 mg/dL) and electrolytes; wherein said composition can be used as a peritoneal dialysate (see col. 2, lines 5 to 46). Furthermore, Isono et al. disclose or suggest that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate (see col. 2, lines 5 to 46, especially lines 34-46). Also, Isono et al. disclose that the peritoneal dialysate can be used to treat acute or chronic peritonitis (see col. 13, lines 47-51 and col. 19, lines 50-53). In addition, Isono et al. disclose that organic acids such as lactic acid an citric acid can be used (see col. 2, lines 5 to 46, especially lines 34-46). This suggests that said peritoneal composition or dialysate by Isono et al. can be administered into the peritoneal cavity

to treat peritoneal injuries or peritoneal cell injuries such as peritonitis. It should be noted that the examiner considers peritonitis as a peritoneal injury or peritoneal cell injury. In fact, it should be noted that applicants acknowledge in their specification that examples of the peritoneal injuries include peritonitis, sclerotic encysted peritonitis, intractable prolonged peritonitis, and general peritonitis (see page 2, paragraph [0026] of applicants' specification).

The difference between applicant's method and the method suggested by Isono et al. is that Isono et al.'s composition does not contain adenosine triphosphate. However, Isono et al. disclose or suggest that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate (see col. 2, lines 5 to 46, especially lines 34-46).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Isono et al., to treat peritoneal injury or a cell injury in a subject by administering a composition comprising a combination of adenosine triphosphate, glucose, and electrolytes as a peritoneal dialysate into the peritoneal cavity of said subject.

One having ordinary skill in the art would have been motivated in view of Isono et al., to treat peritoneal injury or a cell injury in a subject by administering a composition comprising a combination of adenosine triphosphate, glucose, and electrolytes as a peritoneal dialysate into the peritoneal cavity of said subject. It should be noted that it is obvious to a skilled artisan to prepare said peritoneal dialysate or composition with osmotic pressure or osmolarity that would physiological compatible when administered to said subject. It should be noted that the use of peritoneal dialysis to treat patients with renal disease is the extremely common in the art and is well within the purview of a skilled artisan.

Claim 18 is drawn to a treating method for peritoneal injury, characterized by administering an effective amount of adenosine triphosphate or a salt thereof to a subject in need thereof. Claim 19 is drawn to a treating method for cell injury caused by sugar, characterized by administering an effective amount of adenosine triphosphate or a salt thereof to a subject in need thereof. Claim 20 is drawn to the method as described in claim 19, wherein the cell injury caused by sugar is peritoneal mesothelial cell injury caused by glucose. Claims 31-32 are drawn to said method comprising administering a solution containing ATP or salt thereof, glucose of specific concentration range, and electrolytes.

Isono et al. disclose a peritoneal dialysate composition comprising 1 to 8 g/dL glucose (i.e., 1,000- 8000 mg/dL) and electrolytes; wherein said composition can be used as a peritoneal dialysate (see col. 2, lines 5 to 46). Furthermore, Isono et al. disclose or suggest that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate (see col. 2, lines 5 to 46, especially lines 34-46). Also, Isono et al. disclose that the peritoneal dialysate can be used to treat acute or chronic peritonitis (see col. 13, lines 47-51 and col. 19, lines 50-53). In addition, Isono et al. disclose that organic acids such as lactic acid an citric acid can be used (see col. 2, lines 5 to 46, especially lines 34-46). This suggests that said peritoneal composition or dialysate by Isono et al. can be administered into the peritoneal cavity to treat peritoneal injuries or peritoneal cell injuries such as peritonitis. It should be noted that the examiner considers peritonitis as a peritoneal injury or peritoneal cell injury. In fact, it should be noted that applicants acknowledge in their specification that examples of the peritoneal injuries include peritonitis, sclerotic encysted peritonitis, intractable prolonged peritonitis, and general peritonitis (see page 2, paragraph [0026] of applicants' specification).

The difference between applicant's method and the method suggested by Isono et al. is that Isono et al.'s composition does not contain adenosine triphosphate. However, Isono et al. disclose or suggest that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate ((see col. 2, lines 5 to 46, especially lines 34-46).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Isono et al., to treat peritoneal injury or a cell injury in a subject by administering a composition comprising a combination of adenosine triphosphate, glucose, and electrolytes as a peritoneal dialysate into the peritoneal cavity of said subject.

One having ordinary skill in the art would have been motivated in view of Isono et al., to treat peritoneal injury or a cell injury in a subject by administering a composition comprising a combination of adenosine triphosphate, glucose, and electrolytes as a peritoneal dialysate into the peritoneal cavity of said subject. It should be noted that it is obvious to a skilled artisan to prepare said peritoneal dialysate or composition with osmotic pressure or osmolarity that would physiological compatible when administered to said subject. It should be noted that the use of peritoneal dialysis to treat patients with renal disease is the extremely common in the art and is well within the purview of a skilled artisan. It should be noted that it is obvious to a skilled artisan to prepare said peritoneal dialysate or composition with osmotic pressure or osmolarity that would physiological compatible when administered to said subject.

In claim 21, applicant claims a peritoneal dialysis method for treating a peritoneal injury or for treating a cell injury caused by sugar, comprising: administering into the peritoneal cavity of a subject having a peritoneal injury or a cell injury caused by sugar an effective amount of a composition comprising adenosine triphosphate or a salt thereof. Claims 22-30 are drawn to said

method wherein said composition used contains specific electrolytes, organic acid, lactic acid and which has specific osmotic pressure, and wherein the subject has specific conditions.

Isono et al. disclose a peritoneal dialysate composition comprising 1 to 8 g/dL glucose (i.e., 1,000- 8000 mg/dL) and electrolytes; wherein said composition can be used as a peritoneal dialysate (see col. 2, lines 5 to 46). Furthermore, Isono et al. disclose or suggest that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate (see col. 2, lines 5 to 46, especially lines 34-46). Also, Isono et al. disclose that the peritoneal dialysate can be used to treat acute or chronic peritonitis (see col. 13, lines 47-51 and col. 19, lines 50-53). In addition, Isono et al. disclose that organic acids such as lactic acid an citric acid can be used (see col. 2, lines 5 to 46, especially lines 34-46). This suggests that said peritoneal composition or dialysate by Isono et al. can be administered into the peritoneal cavity to treat peritoneal injuries or peritoneal cell injuries such as peritonitis. It should be noted that the examiner considers peritonitis as a peritoneal injury or peritoneal cell injury. In fact, it should be noted that applicants acknowledge in their specification that examples of the peritoneal injuries include peritonitis, sclerotic encysted peritonitis, intractable prolonged peritonitis, and general peritonitis (see page 2, paragraph [0026] of applicants' specification).

The difference between applicant's method and the method suggested by Isono et al. is that Isono et al.'s composition does not contain adenosine triphosphate. However, Isono et al. disclose or suggest that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate ((see col. 2, lines 5 to 46, especially lines 34-46)

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Isono et al., to treat peritoneal injury or a cell injury in a

subject by administering a composition comprising a combination of adenosine triphosphate, glucose, and electrolytes as a peritoneal dialysate into the peritoneal cavity of said subject.

One having ordinary skill in the art would have been motivated in view of Isono et al., to treat peritoneal injury or a cell injury in a subject by administering a composition comprising a combination of adenosine triphosphate, glucose, and electrolytes as a peritoneal dialysate into the peritoneal cavity of said subject. It should be noted that it is obvious to a skilled artisan to prepare said peritoneal dialysate or composition with osmotic pressure or osmolarity that would physiological compatible when administered to said subject. It should be noted that the use of peritoneal dialysis to treat patients with renal disease is the extremely common in the art and is well within the purview of a skilled artisan. It should be noted that it is obvious to a skill artisan to prepare said peritoneal dialysate or composition with osmotic pressure or osmolarity that would physiological compatible when administered to said subject.

Claim 33 is drawn to a peritoneal dialysis method comprising: administering to a patient in need of dialysis a dialysate comprising adenosine triphosphate or a salt thereof. Claims 34 is drawn to the method of claim 33 comprising administering specific dialysate that does not contain ATP and ATP. Claim 35 and 36 are drawn to the said method wherein the adenosine triphosphate is of specific concentration range and wherein the said patient has specific condition,

Isono et al. disclose a peritoneal dialysate composition comprising 1 to 8 g/dL glucose (i.e., 1,000- 8000 mg/dL) and electrolytes; wherein said composition can be used as a peritoneal dialysate (see col. 2, lines 5 to 46). Furthermore, Isono et al. disclose or suggest that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal

dialysate (see col. 2, lines 5 to 46, especially lines 34-46). Also, Isono et al. disclose that the peritoneal dialysate can be used to treat acute or chronic peritonitis (see col. 13, lines 47-51 and col. 19, lines 50-53). In addition, Isono et al. disclose that organic acids such as lactic acid an citric acid can be used (see col. 2, lines 5 to 46, especially lines 34-46). This suggests that said peritoneal composition or dialysate by Isono et al. can be administered into the peritoneal cavity to treat peritoneal injuries or peritoneal cell injuries such as peritonitis. It should be noted that the examiner considers peritonitis as a peritoneal injury or peritoneal cell injury. In fact, it should be noted that applicants acknowledge in their specification that examples of the peritoneal injuries include peritonitis, sclerotic encysted peritonitis, intractable prolonged peritonitis, and general peritonitis (see page 2, paragraph [0026] of applicants' specification).

The difference between applicant's method and the method suggested by Isono et al. is that Isono et al.'s composition does not contain adenosine triphosphate. However, Isono et al. disclose or suggest that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate (see col. 2, lines 5 to 46, especially lines 34-46).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Isono et al., to use a peritoneal dialysis method comprising to treat peritoneal injury such as peritonitis in a subject by administering a composition comprising a combination of adenosine triphosphate, glucose, and electrolytes as a peritoneal dialysate into the peritoneal cavity of said subject.

One having ordinary skill in the art would have been motivated in view of Isono et al., to use a peritoneal dialysis method comprising to treat peritoneal injury such as peritonitis in a subject by administering a composition comprising a combination of adenosine triphosphate,

glucose, and electrolytes as a peritoneal dialysate into the peritoneal cavity of said subject. It should be noted that it is obvious to a skilled artisan to prepare said peritoneal dialysate or composition with osmotic pressure or osmolarity that would physiological compatible when administered to said subject. It should be noted that the use of peritoneal dialysis to treat patients with renal disease is the extremely common in the art and is well within the purview of a skilled artisan. It should be noted that it is obvious to a skill artisan to prepare said peritoneal dialysate or composition with osmotic pressure or osmolarity that would physiological compatible when administered to said subject. Also, it should be noted that it is obvious to use additional dialysate that contains other ingredients like those suggested by Isono et al. based on need such as the severity of the condition and the type, age and weight of the patient treated.

Response to Arguments

Applicant's arguments with respect to claims 11-36 have been considered but are not found convincing.

The Applicant argues that the Examiner has misinterpreted the disclosure of Isono, et al., which is focused describing medical containers, as disclosing (i) a method for treating subjects having peritoneal injury using (ii) a peritoneal dialysate containing adenosine triphosphate (ATP). The Examiner is wrong on both points since Isono does not disclose subjects having peritoneal injury, nor does it disclose a peritoneal dialysate containing ATP.

However, the Examiner has **not** misinterpreted the disclosure of Isono, et al. because Isono et al. disclose a peritoneal dialysate composition comprising 1 to 8 g/dL glucose (i.e., 1,000- 8000 mg/dL) and electrolytes; wherein said composition can be used as a peritoneal dialysate (see col. 2, lines 5 to 46). Furthermore, Isono et al. disclose or suggest that adenosine

triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate (see col. 2, lines 5 to 46, especially lines 34-46). Also, Isono et al. disclose that the peritoneal dialysate can be used to treat acute or chronic peritonitis (see col. 13, lines 47-51 and col. 19, lines 50-53). This suggests that said peritoneal composition or dialysate of Isono et al. can be administered into the peritoneal cavity to treat peritoneal injuries or peritoneal cell injuries such as peritonitis. It should be noted that the examiner considers peritonitis as a peritoneal injury or peritoneal cell injury. In fact, it should be noted that applicants acknowledge in their specification that examples of the peritoneal injuries include peritonitis, sclerotic encysted peritonitis, intractable prolonged peritonitis, and general peritonitis (see page 2, paragraph [0026] of applicants' specification).

Furthermore, Fig. 13 (see sheet 12 of 12) indicates or suggests that the peritoneal dialysate composition can be administered to a patient abdomen, or peritoneum or peritoneal cavity via the depicted dialysate container (see also col. 4, lines 10-12). Moreover, Isono et al. disclose that the medical container according to the present invention is provided with the isolated or connected compartment. The bicarbonate is stored in the compartment. This bicarbonate is mixed with the electrolyte solution (i.e., the base solution) when the openable means is opened at the time of use. As a consequence, the electrolyte (i.e., infusion solution, dialysate or organ-preserving solution) which is used for administration, dialysis or the like contains bicarbonate ions at the time of use. Described specifically, the amount of an electrolyte such as an acetate or a lactate can be reduced in accordance with the proportion of the bicarbonate so that bicarbonate ions are **directly introduced into the body to maintain** the in vivo concentration of bicarbonate ions constant (see col. 4, lines 17-34). Thus, the fact that

Isono et al. disclose that bicarbonate and the electrolyte (i.e., infusion solution, dialysate or organ-preserving solution) solutions are mixed for administration, dialysis or the like and then directly introduced in the body (see col. 4, lines 17-34), means or suggests that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate (see col. 2, lines 5 to 46, especially lines 34-46).

That is, based on Isono et al., the electrolyte solution which includes (i.e., infusion solution, dialysate or organ-preserving solution (which includes the ATP)) is mixed with the bicarbonate for administration and is introduced (or administered) in the body. This means that the solutions are administered to the body and are used for the same purpose or treatment.

The Applicant argues that Isono is totally silent about treating subjects having peritoneal injury even though it discloses conventional dialysis solutions not containing ATP. Isono is also totally silent about peritoneal dialysate solution or methods of peritoneal dialysis using a dialysis solution containing ATP.

However as set forth in the above rejection, Isono et al. disclose a peritoneal dialysate composition comprising 1 to 8 g/dL glucose (i.e., 1,000- 8000 mg/dL) and electrolytes; wherein said composition can be used as a peritoneal dialysate (see col. 2, lines 5 to 46). Furthermore, Isono et al. disclose or suggest that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate (see col. 2, lines 5 to 46, especially lines 34-46). Also, Isono et al. disclose that the peritoneal dialysate can be used to treat acute or chronic peritonitis (see col. 13, lines 47-51 and col. 19, lines 50-53). In addition, Isono et al. disclose that organic acids such as lactic acid an citric acid can be used (see col. 2, lines 5 to 46, especially lines 34-46). This suggests that said peritoneal composition or dialysate

by Isono et al. can be administered into the peritoneal cavity to treat peritoneal injuries or peritoneal cell injuries such as peritonitis.

The Applicant argues that Isono does disclose and exemplifies an organ-preservation solution that optionally may contain ATP but is silent about administering organ-preservation solutions to dialysis patients having peritoneal injuries. As discussed below, no responsible medical practitioner would administer an organ-preservation solution to a dialysis patient.

However, Isono et al. disclose a peritoneal dialysate composition comprising 1 to 8 g/dL glucose (i.e., 1,000- 8000 mg/dL) and electrolytes; wherein said composition can be used as a peritoneal dialysate (see col. 2, lines 5 to 46). Furthermore, Isono et al. disclose or suggest that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate (see col. 2, lines 5 to 46, especially lines 34-46). Also, Isono et al. disclose that the peritoneal dialysate can be used to treat acute or chronic peritonitis (see col. 13, lines 47-51 and col. 19, lines 50-53). This suggests that said peritoneal composition or dialysate of Isono et al. can be administered into the peritoneal cavity to treat peritoneal injuries or peritoneal cell injuries such as peritonitis. It should be noted that the examiner considers peritonitis as a peritoneal injury or peritoneal cell injury. In fact, it should be noted that applicants acknowledge in their specification that examples of the peritoneal injuries include peritonitis, sclerotic encysted peritonitis, intractable prolonged peritonitis, and general peritonitis (see page 2, paragraph [0026] of applicants' specification).

Furthermore, Fig. 13 (see sheet 12 of 12) indicates or suggests that the peritoneal dialysate composition can be administered to a patient abdomen, or peritoneum or peritoneal cavity via the depicted dialysate container (see also col. 4, lines 10-12). Moreover, Isono et al.

disclose that the medical container according to the present invention is provided with the isolated or connected compartment. The bicarbonate is stored in the compartment. This bicarbonate is mixed with the electrolyte solution (i.e., the base solution) when the openable means is opened at the time of use. As a consequence, the electrolyte (i.e., infusion solution, dialysate or organ-preserving solution) which is used for administration, dialysis or the like contains bicarbonate ions at the time of use. Described specifically, the amount of an electrolyte such as an acetate or a lactate can be reduced in accordance with the proportion of the bicarbonate so that bicarbonate ions are **directly introduced into the body to maintain** the in vivo concentration of bicarbonate ions constant (see col. 4, lines 17-34). Thus, the fact that Isono et al. disclose that bicarbonate and the electrolyte (i.e., infusion solution, dialysate or organ-preserving solution) solutions are mixed for administration, dialysis or the like and then directly introduced in the body (see col. 4, lines 17-34), means or suggests that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate (see col. 2, lines 5 to 46, especially lines 34-46). That is, based on Isono et al., the electrolyte solution which includes (i.e., infusion solution, dialysate or organ-preserving solution (which includes the ATP)) is mixed with the bicarbonate for administration and is introduced (or administered) in the body. This means that the solutions are administered to the body and are used for the same purpose or treatment.

The Applicant argues that there is no support for the Examiner's assertion that Isono discloses or suggests that adenosine triphosphate solution "can be added to said peritoneal dialysate".

However, as set forth in the rejection above, Isono et al. disclose a peritoneal dialysate composition comprising 1 to 8 g/dL glucose (i.e., 1,000- 8000 mg/dL) and electrolytes; wherein said composition can be used as a peritoneal dialysate (see col. 2, lines 5 to 46). Furthermore, Isono et al. disclose or suggest that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate (see col. 2, lines 5 to 46, especially lines 34-46). In addition, Isono et al. disclose that organic acids such as lactic acid an citric acid can be used (see col. 2, lines 5 to 46, especially lines 34-46). This suggests that said peritoneal composition disclosed by Isono et al. can be administered into the peritoneal cavity (see rejection above).

Furthermore, Fig. 13 (see sheet 12 of 12) indicates or suggests that the peritoneal dialysate composition can be administered to a patient abdomen, or peritoneum or peritoneal cavity via the depicted dialysate container (see also col. 4, lines 10-12). Moreover, Isono et al. disclose that the medical container according to the present invention is provided with the isolated or connected compartment. The bicarbonate is stored in the compartment. This bicarbonate is mixed with the electrolyte solution (i.e., the base solution) when the openable means is opened at the time of use. As a consequence, the electrolyte (i.e., infusion solution, dialysate or organ-preserving solution) which is used for administration, dialysis or the like contains bicarbonate ions at the time of use. Described specifically, the amount of an electrolyte such as an acetate or a lactate can be reduced in accordance with the proportion of the bicarbonate so that bicarbonate ions are **directly introduced into the body to maintain** the in vivo concentration of bicarbonate ions constant (see col. 4, lines 17-34). Thus, the fact that Isono et al. disclose that bicarbonate and the electrolyte (i.e., infusion solution, dialysate or

organ-preserving solution) solutions are mixed for administration, dialysis or the like and then directly introduced in the body (see col. 4, lines 17-34), means or suggests that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate (see col. 2, lines 5 to 46, especially lines 34-46). That is, based on Isono et al., the electrolyte solution which includes (i.e., infusion solution, dialysate or organ-preserving solution (which includes the ATP)) is mixed with the bicarbonate for administration and is introduced (or administered) in the body. This means that the solutions are administered to the body and are used for the same purpose or treatment.

The Applicant argues that as clearly exemplified by Isono in col. 2, peritoneal dialysates and organ-preserving solutions contain different ingredients, for example, a peritoneal dialysate contains high concentrations of glucose not present in the organ-preserving solution described by Isono and lacks the heparin found in organ preserving solution exemplified by Isono. The paragraphs in col. 2, lines 22-47 of Isono describe ingredients commonly found in organ-preserving solutions including anticoagulants like heparin. ATP is disclosed at col. 2, line 41 as one possible ingredient of an preserving solution. ATP is simply not disclosed as an ingredient of a peritoneal dialysate. There is no support for the Examiner's assertion that Isono discloses or suggests that adenosine triphosphate solution "can be added to said peritoneal dialysate". Moreover, Isono does not confuse these different types of electrolyte solutions and no one skilled in the medical arts would have confused them.

However, Isono et al. disclose or suggest that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate (see col. 2, lines 5 to 46, especially lines 34-46). Also, Isono et al. disclose that the peritoneal dialysate can be used to

treat acute or chronic peritonitis (see col. 13, lines 47-51 and col. 19, lines 50-53). This suggests that said peritoneal composition or dialysate of Isono et al. can be administered into the peritoneal cavity to treat peritoneal injuries or peritoneal cell injuries such as peritonitis. It should be noted that the examiner considers peritonitis as a peritoneal injury or peritoneal cell injury. In fact, it should be noted that applicants acknowledge in their specification that examples of the peritoneal injuries include peritonitis, sclerotic encysted peritonitis, intractable prolonged peritonitis, and general peritonitis (see page 2, paragraph [0026] of applicants' specification). In addition, the fact that Isono et al. disclose that bicarbonate and the electrolyte (i.e., infusion solution, dialysate or organ-preserving solution) solutions are mixed for administration, dialysis or the like and then directly introduced in the body (see col. 4, lines 17-34), means or suggests that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate (see col. 2, lines 5 to 46, especially lines 34-46). That is, based on Isono et al., the electrolyte solution which includes (i.e., infusion solution, dialysate or organ-preserving solution (which includes the ATP)) is mixed with the bicarbonate for administration and is introduced (or administered) in the body. This means that the solutions are administered to the body and are used for the same purpose or treatment.

The Applicant argues that Isono is primarily directed to a medical container containing an electrolyte solution and is not directed to formulating new types of electrolyte solutions. In conjunction with disclosure of the container, Isono incidentally describes different types of electrolyte solutions that the medical container might hold such as "a body fluid replenisher", "a dialysate" and "an electrolyte solution", it does not disclose a peritoneal dialysate solution containing ATP, does not provide any motivation for adding ATP to a peritoneal dialysate, and

consequently, cannot provide a reasonable expectation for the superior properties of a peritoneal dialysate containing ATP.

However, Isono et al. disclose or suggest that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate (see col. 2, lines 5 to 46, especially lines 34-46). Also, Isono et al. disclose that the peritoneal dialysate can be used to treat acute or chronic peritonitis (see col. 13, lines 47-51 and col. 19, lines 50-53). This suggests that said peritoneal composition or dialysate of Isono et al. can be administered into the peritoneal cavity to treat peritoneal injuries or peritoneal cell injuries such as peritonitis. It should be noted that the examiner considers peritonitis as a peritoneal injury or peritoneal cell injury. In fact, it should be noted that applicants acknowledge in their specification that examples of the peritoneal injuries include peritonitis, sclerotic encysted peritonitis, intractable prolonged peritonitis, and general peritonitis (see page 2, paragraph [0026] of applicants' specification). In addition, the fact that Isono et al. disclose that bicarbonate and the electrolyte (i.e., infusion solution, dialysate or organ-preserving solution) solutions are mixed for administration, dialysis or the like and then directly introduced in the body (see col. 4, lines 17-34), means or suggests that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate (see col. 2, lines 5 to 46, especially lines 34-46). That is, based on Isono et al., the electrolyte solution which includes (i.e., infusion solution, dialysate or organ-preserving solution (which includes the ATP)) is mixed with the bicarbonate for administration and is introduced (or administered) in the body. This means that the solutions are administered to the body and are used for the same purpose or treatment.

The Applicant argues that Isono fails to provide any motivation for adding ATP to a peritoneal dialysis solution or any reasonable expectation of success for reducing injury to patients undergoing peritoneal dialysis by doing so.

However as set forth in the above rejection, Isono et al. disclose a peritoneal dialysate composition comprising 1 to 8 g/dL glucose (i.e., 1,000- 8000 mg/dL) and electrolytes; wherein said composition can be used a peritoneal dialysate (see col. 2, lines 5 to 46). Furthermore, Isono et al. disclose or suggest that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate (see col. 2, lines 5 to 46, especially lines 34-46). Also, Isono et al. disclose that the peritoneal dialysate can be used to treat acute or chronic peritonitis (see col. 13, lines 47-51 and col. 19, lines 50-53). In addition, Isono et al. disclose that organic acids such as lactic acid an citric acid can be used (see col. 2, lines 5 to 46, especially lines 34-46). This suggests that said peritoneal composition or dialysate by Isono et al. can be administered into the peritoneal cavity to treat peritoneal injuries or peritoneal cell injuries such as peritonitis. Consequently, one having ordinary skill in the art would have been motivated in view of Isono et al., to treat peritoneal injury or a cell injury in a subject by administering a composition comprising a combination of adenosine triphosphate, glucose, and electrolytes as a peritoneal dialysate into the peritoneal cavity of said subject.

The Applicant argues that the Office's conflation of a dialysis solution with an organ-preservation solution is improper and cannot support a primafacie basis for an obviousness rejection. While the final Official Action ("OA") explicitly states that "Isono et al.'s composition does not contain adenosine triphosphate" (OA, bottom of page 3), it contends that such a dialysis solution is suggested by Isono. However, Isono clearly distinguishes amongst the different

physiological solutions that may be contained within the medical container it discloses. Namely, cols. 1 and 2 of Isono distinguish between (i) infusion solutions, (ii) dialysate, and (iii) an organ (tissue) preserving solution, see col. 1, lines 21-24, and col. 1, lines 51-col. 2, line 4 describing infusion solutions, col. 2, lines 5-21 which disclose dialysates, and col. 2, lines 35-47 which describe organ-preserving solutions. It is evident from these portions of the reference that Isono recognized the significant compositional differences between a peritoneal dialysis solution and one used to preserve organs.

However as set forth in the above rejection, Isono et al. disclose a peritoneal dialysate composition comprising 1 to 8 g/dL glucose (i.e., 1,000- 8000 mg/dL) and electrolytes; wherein said composition can be used a peritoneal dialysate (see col. 2, lines 5 to 46). Furthermore, Isono et al. disclose or suggest that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate (see col. 2, lines 5 to 46, especially lines 34-46). Also, Isono et al. disclose that the peritoneal dialysate can be used to treat acute or chronic peritonitis (see col. 13, lines 47-51 and col. 19, lines 50-53). In addition, Isono et al. disclose that organic acids such as lactic acid an citric acid can be used (see col. 2, lines 5 to 46, especially lines 34-46). This suggests that said peritoneal composition or dialysate by Isono et al. can be administered into the peritoneal cavity to treat peritoneal injuries or peritoneal cell injuries such as peritonitis. Moreover, Isono et al. disclose that the medical container according to the present invention is provided with the isolated or connected compartment. The bicarbonate is stored in the compartment. This bicarbonate is mixed with the electrolyte solution (i.e., the base solution) when the openable means is opened at the time of use. As a consequence, the electrolyte (i.e., infusion solution, dialysate or organ-preserving

solution) which is used for administration, dialysis or the like contains bicarbonate ions at the time of use. Described specifically, the amount of an electrolyte such as an acetate or a lactate can be reduced in accordance with the proportion of the bicarbonate so that bicarbonate ions are **directly introduced into the body to maintain** the in vivo concentration of bicarbonate ions constant (see col. 4, lines 17-34). Thus, the fact that Isono et al. disclose that bicarbonate and the electrolyte (i.e., infusion solution, dialysate or organ-preserving solution) solutions are mixed for administration, dialysis or the like and then directly introduced in the body (see col. 4, lines 17-34), means or suggests that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate (see col. 2, lines 5 to 46, especially lines 34-46).

The Applicant argues that the Examiner has not pointed out any other portion of Isono suggesting administering "a dialysate comprising adenosine triphosphate" to a patient having a peritoneal injury or cell injury caused by sugar" as required by independent claim 11.

However, Isono et al. suggest treating the same condition that is treated by applicant regardless of the cause of said condition. As example, Isono et al. disclose a peritoneal dialysate composition comprising 1 to 8 g/dL glucose (i.e., 1,000- 8000 mg/dL) and electrolytes; wherein said composition can be used a peritoneal dialysate (see col. 2, lines 5 to 46). Furthermore, Isono et al. disclose or suggest that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate (see col. 2, lines 5 to 46, especially lines 34-46). Also, Isono et al. disclose that the peritoneal dialysate can be used to treat acute or chronic peritonitis (see col. 13, lines 47-51 and col. 19, lines 50-53). This suggests that said peritoneal composition or dialysate by Isono et al. can be administered into the

peritoneal cavity to treat peritoneal injuries or peritoneal cell injuries such as peritonitis. It should be noted that the examiner considers peritonitis as a peritoneal injury or peritoneal cell injury. In fact, it should be noted that applicants acknowledge in their specification that examples of the peritoneal injuries include peritonitis, sclerotic encysted peritonitis, intractable prolonged peritonitis, and general peritonitis (see page 2, paragraph [0026] of applicants' specification).

The Applicant argues that adenosine triphosphate is not recognized as a conventional component of dialysis solution as evident from the citations below: (1) Wikipedia "Peritoneal dialysis" (ii) Package inserts (Japanese/English) from Baxter Healthcare Corporation describing components of a peritoneal dialysis solution: see evidence appendix) and (iii) Technical literature from Baxter Healthcare Corporation "Pertioneal Dialysis PD Solutions" (see evidence appendix).

However, Isono et al. disclose a peritoneal dialysate composition comprising 1 to 8 g/dL glucose (i.e., 1,000- 8000 mg/dL) and electrolytes; wherein said composition can be used a peritoneal dialysate (see col. 2, lines 5 to 46). Furthermore, Isono et al. disclose or suggest that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate (see col. 2, lines 5 to 46, especially lines 34-46). Also, Isono et al. disclose that the peritoneal dialysate can be used to treat acute or chronic peritonitis (see col. 13, lines 47-51 and col. 19, lines 50-53). In addition, Isono et al. disclose that organic acids such as lactic acid an citric acid can be used (see col. 2, lines 5 to 46, especially lines 34-46). This suggests that said peritoneal composition or dialysate by Isono et al. can be administered into the peritoneal cavity to treat peritoneal injuries or peritoneal cell injuries such as peritonitis. Also, Isono et al. disclose that the medical container according to the present invention is provided

with the isolated or connected compartment. The bicarbonate is stored in the compartment. This bicarbonate is mixed with the electrolyte solution (i.e., the base solution) when the openable means is opened at the time of use. As a consequence, the electrolyte (i.e., infusion solution, dialysate or organ-preserving solution) which is used for administration, dialysis or the like contains bicarbonate ions at the time of use. Described specifically, the amount of an electrolyte such as an acetate or a lactate can be reduced in accordance with the proportion of the bicarbonate so that bicarbonate ions are **directly introduced into the body to maintain** the in vivo concentration of bicarbonate ions constant (see col. 4, lines 17-34). Thus, the fact that Isono et al. disclose that bicarbonate and the electrolyte (i.e., infusion solution, dialysate or organ-preserving solution) solutions are mixed for administration, dialysis or the like and then directly introduced in the body (see col. 4, lines 17-34), means or suggests that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate (see col. 2, lines 5 to 46, especially lines 34-46).

The Applicant argues that Claim 34 was rejected under 35 U.S.C. 112, second paragraph, as indefinite for use of the phrase "a conventional peritoneal dialysis solution that does not contain adenosine triphosphate and adenosine triphosphate". This phrase simply refers to a composition containing two components (i) a conventional peritoneal dialysis solution that does not contain adenosine triphosphate" and (ii) adenosine triphosphate which together provide "a peritoneal dialysate containing ATP" as disclosed on page 3, lines 11-12 of the specification. Page 9, 2nd paragraph, of the specification also discloses admixture of a conventional dialysate with adenosine triphosphate.

However, the claim is indefinite since it is unclear how **a solution** can contain and simultaneously not contain the same substance or ingredient (adenosine triphosphate). That is, a peritoneal dialysate (**a solution**) or **a** peritoneal dialysis **solution** cannot have the same substance (i.e., ATP) in the solution being present and absent at the same time (simultaneously).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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April 13, 2011.

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